



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 21 2002

Mr. Rafic Saleh
President
Horizons International Corp.
287 Monterrey Street
PONCE PR 00717-1376

Re: K021706
Trade/Device Name: Horizons Hot Biopsy Forceps
Regulation Number: 21 CFR 876.4300
Regulation Name: Endoscopic electrosurgical
unit and accessories
Regulatory Class: II
Product Code: 78 KGE
Dated: May 14, 2002
Received: May 23, 2002

Dear Mr. Saleh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

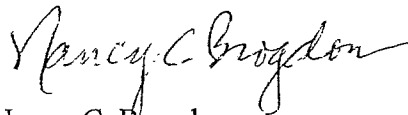
This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

6.1 Indication for Use

510K INDICATION FOR USE STATEMENT

510(k) Number (if known): K021706

Device Name: Horizons Hot Biopsy Forceps

Applicant Name: Horizons International Corp.

Indications for Use:

Horizons Hot Biopsy Forceps is intended to be used in the flexible endoscope for transendoscopic, dissecting, and grasping tissue for biopsy.

Horizons International Corp.

Signature:

Rafic Saleh – President

Date:

2/18/02

Prescription Use ☒
(Per 21 CFR 801.109)

(Division Sign-Off)

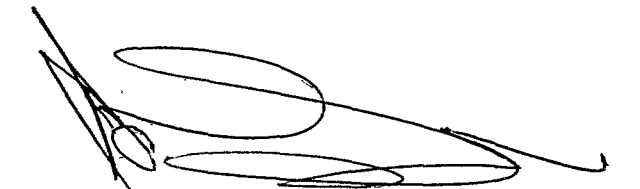
Division of Reproductive, Abdominal,
and Radiological Devices

510(k) Number

K021706

510K STATEMENT OF SAFETY AND EFFECTIVENESS:

I certify, in my capacity as President of Horizons International Corporation, I will make available all information included in this premarket notification on safety and effectiveness within 30 days of request by any person if the device is determined to be substantially equivalent. The information made available will be a duplicate of the premarket notification submission, including any adverse safety and effectiveness information, but excluding all patient identifiers, and trade secret and confidential commercial information, as defined in 21CFR20.61.



Rafic Saleh – President

5/22/02

Date